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PRINCIPAL INVESTIGATOR Barbara Stanley, Ph.D.

CONTRACTING ORGANIZATION: Research Foundation for Mental Hygiene
New York, NY 10032

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6. AUTHOR(S) Gregory K. Brown, Ph.D., Marjan G. Holloway, Ph.D., Barbara Stanley, Ph.D.(CONTACT PI) E-Mail: gregbrow@mail.med.upenn.edu , marjan.holloway@usuhs.edu , bhs2@columbia.edu				5d. PROJECT NUMBER	
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14. ABSTRACT The broad objective of this project is to provide Army leaders, behavioral health providers and chaplains with targeted, practical, and scientifically-informed guidelines and decision aids on how to respond to suicide-related events during deployment. The study is being conducted in three stages. Stage 1 consists of interviews and focus groups with previously deployed behavioral health providers, chaplains, and unit leaders, as well as Service Members with documented suicide-related events during their deployment. In Stage 2, we will conduct a web-based survey of behavioral health providers, chaplains, and leaders in order to determine the types of decisions made in relation to suicide-related events; identify the methods of decision making for each subgroup in relation to these events; and summarize lessons learned from the outcomes of these decisions. In Stage 3, the qualitative and quantitative data will be synthesized and reported to the Expert Advisory Panel in order to develop guidelines and decision aids for use by providers, leaders and chaplains. Over the past year, our efforts have focused on Stage 1 of the study. We have gained regulatory approvals from the appropriate institutions, developed survey instruments, trained interviewers and coders, administered pilot interviews, and begun subject recruitment and enrollment.					
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Introduction

Suicide has historically ranked as the second leading cause of death in the United States military.¹ While the relationship between deployment and suicide is not yet clearly understood, recent data indicate that suicide in the Army is highest during deployment.² Not much is known about how three types of suicide-related events, (1) suicides, (2) suicide-related behaviors (defined here as: (a) serious suicide ideation with a plan and intent to die; (b) suicide attempts; (c) suicidal behavior that stops short of an attempt (e.g., interrupted attempts)), and (3) suicide-related evacuations, are handled in deployed settings. Furthermore, not much is known about 1) the impact of these decisions on deployed Service Members who are in the suicidal Service Member's unit; 2) whether the decision-making process affects suicidality in the unit; and 3) the impact of suicide-related events on the military personnel involved in decision-making surrounding the suicidal behavior. To date, there are no standardized and systematic procedures within the DoD for the handling of suicide-related events that occur during deployment, nor is there a military-specific empirical base from which to develop these procedures. The broad objective of this project is to provide military leaders, military behavioral health providers (BHPs) and chaplains with a series of targeted, practical, and scientifically-informed guidelines and decision aids for how to best address and respond to suicide-related events during the time of their deployment. In the current project, a mixed methods approach is used to develop these guidelines and decision aids. Stage 1 of the research plan utilizes qualitative methods with the following data sources: (1) confidential interviews with a representative sample of previously deployed behavioral health providers, chaplains, and leaders (Stage 1A); (2) confidential focus groups with a diverse sample of behavioral health providers, chaplains, and leaders (Stage 1B); and (3) confidential interviews with a representative sample of Service Members (Stage 1C) with documented suicide-related events during their deployment. The purpose of Stage 1 data collection is to characterize the most common types of decisions made during the time of deployment pertaining to suicide-related events as well as the possible impact. Stage 2 of the research plan involves designing and administering a comprehensive, anonymous, and confidential survey to a diverse sample of behavioral health providers, chaplains and leaders that will be informed by Stage 1 A, B and C findings. The purpose of the survey is to evaluate the attitudes, opinions, and rationale associated with the most common types of decisions made by behavioral health providers, chaplains, and leaders to address suicide-related evacuations, suicide-related behaviors, and suicide deaths. Stage 3 of the research focuses on the use of the qualitative and quantitative data as the basis of discussion during consensus meetings attended by expert suicidologists, military healthcare specialists, chaplaincy, stakeholders, and military leadership. The data on experiences and lessons learned by various helping professionals and military leaders during their time of deployment combined with the formal review and discussion of this data during the consensus meetings allows for the development of a practical and evidence-informed product for the Army's suicide prevention program. In addition to reports detailing the findings, the study deliverables include a series of clear and feasible "best practices" decision-making guides pertaining to suicide-related events occurring during deployment. These decision aids/guidelines take into consideration the unique needs of military behavioral health providers, chaplains, and leaders in the Army. Best practice guidelines or decision aids produced as a result of this study serve to promote an evidence-informed and standardized manner to handle suicide-related events in the Army during the critical period of deployment.

Body

This project is a collaborative effort among multiple Principal Investigators (PIs) from the University of Pennsylvania (UPenn; Dr. Gregory Brown), the Uniformed Services University of the Health Sciences (USUHS; Dr. Marjan Holloway), and the Columbia University/New York State Psychiatric Institute (CU/NYSPI ; Dr. Barbara Stanley, corresponding PI). The study PIs maintain regular weekly communication via email and conference calls in order to provide oversight for the daily functions of the project and to make timely progress on the stated objectives.

During Year 2, substantial progress was made on Stages 1A (confidential interviews with behavioral health providers, military leaders and chaplains), 1B (focus groups with behavioral health providers, leaders and chaplains) and 1C (confidential interviews with Service Members) of the study. In order to ensure that steady progress was made towards research goals, the study team worked collaboratively and concurrently on the various stages of the project. During the previous reporting period, we obtained regulatory approval for Study 1, which includes both Stages 1A and 1B of this project. Significant effort was made to recruit participants for the Study 1 confidential interviews. The recruitment goal for behavioral health providers was reached, with 16 interviews completed. Approximately half of the recruitment target for military leaders has been met, with 9 interviews completed. In addition, 4 confidential interviews with chaplains have been completed. Recruitment of military leaders and chaplains has been difficult and the study team has made efforts to do additional outreach to meet our goals. The details of these efforts are provided below. The completed confidential interviews were transcribed and analyzed. The coded interviews served to inform the questions developed for the Stage 1B focus groups. With regard to the Study 1 focus groups, during this reporting period, the research team developed the focus group interview, refined our recruitment strategy, and began recruitment of behavioral health providers for the focus groups. The first focus group is scheduled for the start of the next reporting period.

Study 2 involves Stage 1C of the project, the confidential interviews with service members who experienced a suicide-related event during deployment. The focus for Study 2 during this reporting period has been on obtaining regulatory approval through the IRBs at Walter Reed National Military Medical Center (WRNMMC), USUHS, CU/NYSPI, and UPenn, as well as the Human Research Protection Office (HRPO) at the USAMRMC. In addition, study questions were refined; developed study forms, databases and regulatory binders; trained interviewers and prepared for recruitment. Recruitment for Study 2 will begin at the start of the next reporting period.

Key Research Accomplishments

For the second year reporting period (1/15/14-1/14/15), here is a listing of all activities performed by the three study PIs across the three study sites:

Personnel, Training, Cross-Site Communication and Presentation of Findings

1. Hired and Trained Staff at Each Site

Several staff changes have occurred over the past year. New personnel have been hired to replace research staff who have left, and the three sites continue to have a strong research team dedicated to accomplishing study goals.

At the CU/NYSPI site, Sadia Chaudhury, Ph.D. continues to serve as the site's Research Coordinator, under the supervision of the site PI, Dr. Barbara Stanley. Ms. Emily Biggs, a Master's level Research assistant, left her position to attend graduate school. In her place, Ms. Damaris Fuster, MA, and Ms. Ceren Sonmez, MA, have been joined the project. Their responsibilities include assisting Drs. Stanley and Chaudhury on site-specific study activities, including assisting in the recruitment of subjects for Study 1 focus groups, coding interviews, and taking minutes on weekly conference calls.

At the University of Pennsylvania, Dr. Abby Adler continues to serve as the site's Research Coordinator, under the supervision of the site PI, Dr. Gregory Brown. Also, Ashley Mahler, MA, continues to serve as a Research Assistant while Guy Weissinger, a Master's level research staff member, left his position to attend graduate school. Dr. Fran Barg and Ms. Shimrit Keddem have been responsible for providing training and consultation on qualitative analysis. Ms. Keddem left her position in October 2014 and was replaced by Elisabeth Stelson, MSW, LSW, MPH, another member of Dr. Barg's qualitative research methods lab. Mr. Robert Wheeler remains on staff to assist with IRB coordination and reporting requirements among the three sites.

At USUHS, Dr. Laura Neely has been serving as the site's Research Coordinator, under the supervision of Dr. Marjan Holloway. Her responsibilities included coordinating the site's scientific activities, as well as monitoring project timelines, and progress on study-related tasks. Lauren Matthews left her position and was replaced by Victoria Colborn, a bachelor's level Research Assistant who has been responsible for confidential interview recruitment and scheduling. Kari Koss, M.A., a Masters level Research Assistant along with two doctoral military students (working in Kind, LTJG Marcus VanSickle and ENS Kyna Pak) have conducted all of the confidential interviews over the phone. All transcriptions of digitally recorded interviews have been completed at USUHS by several research staff members who have also contributed to qualitative codings on the study. During Robert Wheeler's leave, Kari Koss additionally contributed to the IRB-related efforts on the project. Kanchana Perera, M.SC continues to provide assistance with data management and other study-related tasks as needed.

All new staff members across all three sites have completed the required IRB-related trainings (e.g., CITI) and have been oriented to the objectives of the study.

2. Established Communication across Study Sites – Held Weekly Conference Calls

We continue to hold two weekly conference calls to facilitate communication across sites and ensure study progress on both study-specific and site-specific tasks. The first of these calls is the Study PI Coordination Calls, during which the three project Principal Investigators, Drs. Brown, Holloway and Stanley, as well as supporting staff from all three sites discuss study-related activities, monitor progress on study-specific and site-specific tasks/deadlines, and problem solve study-related challenges. During the second weekly call, the Research Working Group Calls, the Research Coordinators at each site, along with other study staff, meet to discuss site-specific progress on tasks and to work on specific weekly goals delineated during the PI Coordination Calls. Furthermore, throughout the reporting period, additional conference calls have taken place to develop the interview questions for Study 2 and to prepare materials for regulatory approval.

3. Maintained Contact with Members of the Expert Panel

The Study PIs have remained in contact with members of the expert panel and have kept them updated on study progress. The members of the Expert Panel are Lanny Berman, Ph.D., ABPP; Stephen V. Bowles, Ph.D., ABPP; John Bradley, M.D.; Russell B. Carr, M.D.; Charles C. Engel, M.D., MPH; David A.

Jobes, Ph.D., ABPP; Chris Martin, LCDR; Kim Ruocco, MSW; Gary H. Wynn, M.D.; Richard McKeon, Ph.D., MPH; and Craig Bryan, PsyD. They have continued to reaffirm their willingness to serve on the panel and their commitment to the project.

4. Trained Staff on Qualitative Research Methods and Analysis

Training in qualitative research and analysis has been ongoing. Drs. Fran Barg and members of her lab, Ms. Shimrit Keddem and Ms. Elisabeth Stelson, have provided ongoing consultation on qualitative research questions during the reporting period. In addition, Dr. Adler and Ms. Keddem worked closely with the coders on this study to ensure that coding of the qualitative data from the confidential interviews is being done in an accurate manner. Dr. Adler has been reviewing the coded transcripts on an ongoing basis and providing supervision and training on an as needed basis to the coders to ensure that the coders are both adhering to the codebook and reliable with each other.

5. Presented Study Findings

On February 11 2014, Drs. Stanley, Holloway and Brown presented this study via conference call to the R&A group for Task Area W3 (Deployment). In addition, on May 14 2014, this study was presented at the In Progress Review Meeting of the United States Medical Research and Materiel Command in Fort Detrick, MD. Finally, this study was also presented at the Annual Military Health System Research Symposium in Fort Lauderdale, FL in August 2014.

Study 1: Regulatory Approval and Recruitment

1. Maintained Regulatory Approval of Study 1

IRB approval for Study 1, which includes Stage 1A (confidential interviews with behavioral health providers, chaplains and leaders) and Stage 1B (focus groups with behavioral health providers, chaplains and leaders) of the project, remains up-to-date at all three sites (USUHS, CU/NYSPI, and UPenn). In addition, we continue to have approval through HRPO for all three sites.

2. Recruited Participants for Study 1 Confidential Interviews

Recruitment for the Study 1 confidential interviews with behavioral health providers, chaplains and military leaders is ongoing. During the reporting period, we were able to reach our recruitment target for behavioral health providers (n=15). We have faced significant challenges in the recruitment of leaders and chaplains. In particular, Army chaplains have been hesitant to participate without authorization from the Army Chief of Chaplains office. Therefore, we have taken appropriate steps to address these problems in order to reach our recruitment goals. With regard to the recruitment of Army leaders, Dr. Holloway has been in contact with MAJ Hiatt at the USAMRMC, who has been providing our team with contact information for military leaders who may be eligible for this study. To address the concerns of chaplains, Dr. Holloway has been in communication with COL Kenneth W. Stice, Director, DACH-35/7, Office of the Army Chief of Chaplains, who is second in command for the Army Chief of Chaplains. Dr. Holloway explained the study and its goals to COL Stice. Based on this communication, the Chief of Army Chaplains, CH (MG) Donald Rutherford has looked at the questions on the confidential interviews and approved them for use with Army Chaplains, thus providing support of the Chief of Chaplains' office. COL Stice has offered to distribute the study's recruitment materials to Army Chaplains through his office and has recently designated Mr. Duncan Baugh, retired Army Chaplain and current Strategic Analyst at the Office of the Chief of Chaplains to serve as a liaison and to also serve as a subject matter expert on the study's advisory board. We anticipate that these communications and steps will allow us reach our recruitment goals for leaders and chaplains during the next reporting period.

3. Collected Data from Study 1 Confidential Interviews

Our recruitment goal for the Study 1 confidential interviews is to recruit 15 each of behavioral health providers, leaders, and chaplains. During this reporting period, we successfully completed 16 interviews with behavioral health providers, 9 interviews with leaders, and 4 interviews with chaplains. All of the interviews have been transcribed and coded for qualitative analysis.

4. Analyzed Data from Study 1 Confidential Interviews

Analysis of the confidential interviews has been ongoing during the reporting period. Transcription of completed interviews is being done immediately after an interview is complete. The transcribed interviews are then coded by our coders using NVIVO software. Supervision of the coding process has been provided by Dr. Abby Adler, Ms. Shimrit Keddem and Ms. Elisabeth Stelson as described above (see: Trained Staff on Qualitative Research Methods and Analysis, p. 7). Key themes have been identified. Secondary coding and analysis has also been completed during this reporting period for the interviews with behavioral health providers and leaders. The findings from this analysis helped inform the questions for the Study 1 focus groups with both the behavioral health providers and leaders, as described below.

5. Developed Interview Questions for Study 1 Focus Groups with Behavioral Health Providers

The PIs and research staff worked together to develop the interview questions for the focus group with behavioral health providers. The research team reviewed the key themes that emerged from the analysis of the Study 1 confidential interviews with behavioral health providers. After reviewing the data from each of these themes, taking particular note of issues that were repeatedly identified as problematic, questions were developed to further our understanding of the decision-making process of behavioral health providers when managing suicide-related events in deployed settings. We consulted with our qualitative research advisors, Dr. Barg and Ms. Keddem, to ensure that the finalized questions were appropriate for a focus group setting and that they addressed the research aims of this project.

6. Developed Interview Questions for Study 1 Focus Groups with Military Leaders

The PIs and research staff worked together to develop the interview questions for the focus group with Army leaders. Since recruitment of leaders for the confidential interviews is not yet complete, the PIs decided to develop a preliminary set of questions based on the interviews completed to date, with a plan to review the questions and make necessary changes once the full sample of leaders is recruited. The research team reviewed the key themes that emerged from the analysis of the Study 1 confidential interviews with leaders, with particular focus on problematic issues with the decision-making process as well as differences between the experiences of behavioral health providers and leaders. The focus group questions that were originally created for use with behavioral health providers were revised based on these differences to develop the questions for the military leader focus groups. A similar process will be used to create the questions for the chaplain focus groups during the next reporting period once more chaplains are recruited for the Study 1 confidential interviews.

7. Revised Recruitment Strategy for Study 1 Focus Groups

USUHS has taken the lead on recruitment of participants for the confidential interviews. In order to increase efficiency and distribute tasks evenly between sites, it was decided that CU/NYSPI will take the lead on recruiting and conducting the focus groups. IRB approval was obtained at all three sites for this change in recruitment strategy.

8. Began Recruitment for Study 1 Focus Groups

At the end of this reporting period, recruitment began for the first focus group with behavioral health providers. To date, eight Army behavioral health providers have been screened and provided consent for participating in the study. The first focus group has been scheduled for early in the next reporting period and we are in the process of scheduling the second group with behavioral health providers. During the next reporting period, we also anticipate completing the focus groups with military leaders and chaplains as well.

Study 2: Regulatory Approval Process and Study Design.

1. Prepared IRB Documents for Study 2 for Submission to WRNMMC

During the previous reporting period, the PIs contacted representatives from 1) Walter Reed National Military Medical Center (WRNMMC), 2) the IRB at USUHS, 3) the IRB at CU/NYSPI, 4) the IRB at UPenn, and 5) the HRPO at the USAMRMC Office of Research Protections in order to determine the most efficient manner in submitting and gaining regulatory approvals for the conduct of Study 2, which includes Stage 1C

(confidential interviews with Service Members who experienced a suicide-related event during deployment). Based on this communication, the plan of action for regulatory approval for Study 2 was to first submit the application to the Walter Reed National Military Medical Center (WRNMMC) IRB, then to the USUHS, CU/NYSPI and UPenn IRBs simultaneously, and finally to HRPO. The PIs and study staff worked together to prepare the IRB documents for submission to WRNMMC IRB, including the protocol, letter of support, impact statements, consent form, and CRADA.

2. Developed Interview Questions for Study 2

The PIs and study staff members met regularly during the reporting period to develop the questions for the interviews with Service Members. Dr. Fran Barg and Ms. Shimrit Keddem from the University of Pennsylvania, researchers with extensive expertise in qualitative research methodology, have been actively involved in the development of interview questions.

3. Submitted IRB Application to WRNMMC IRB and Obtained Institutional Approval

The Study 2 protocol was submitted to the WRNMMC IRB on May 19, 2014. Full approval was obtained on September 29, 2014.

4. Submitted IRB Application to USUHS IRB and Obtained Institutional Approval

After receiving approval from WRNMMC IRB, the study application was submitted to the USUHS IRB on October 22, 2014. Full approval was obtained on October 29, 2014.

5. Submitted IRB application to Penn IRB and Obtained Institutional Approval

The study application was submitted simultaneously to Penn IRB on October 15, 2014. The application was reviewed and approved on October 29, 2014.

6. Submitted IRB Application to CU/NYSPI IRB and Obtained Institutional Approval

The Study 2 application was submitted to the CU/NYSPI IRB on 10/20/14. At first review, CU/NYSPI IRB responded with several questions for the Site PI, Dr. Stanley. Dr. Stanley addressed these questions and official approval from NYSPI IRB was received on 12/8/15.

7. Obtained Regulatory Approval from HRPO for All Sites

HRPO reviewed the combined submission of all sites and approved the study as a whole on January 2, 2015.

8. Developed Study Forms, Database and Regulatory Binders for Study 2

In addition to the interview questions and self-report measures for Study 2, a demographic questionnaire was developed and piloted. A database to track recruitment, screening and enrollment of study participants was created. Regulatory binders were also created for Study 2.

9. Completed Pilot Interviews for Study 2

Two pilot interviews were conducted with two goals in mind: 1) to train research staff in the conduct of the interviews; and 2) to allow for further discussion and refinement of the confidential interview questions. We are in the process of shortening and refining the interview questions based on the piloting process.

10. Trained Staff on Study 2 Interview

Three members of the USUHS research team (Dr. Stacy Tylor, CPT Jay Carreno, and ENS Kyna Pak) have been trained to conduct the confidential interviews with Service Members. They will be available to go to the inpatient unit at WRNMMC to conduct the interviews with Service Members. The USUHS team has a representative, Victoria Colborn or another team member, attending morning report at the WRNMMC inpatient psychiatric unit daily in order to keep track of potential study participants and to obtain permission to approach from the potentially eligible patient's provider.

11. Planned Recruitment for Study 2

A planned method of recruitment has been agreed upon by the study PIs. We will recruit Service Members with a history of a suicide-related event during deployment from an inpatient unit on WRNMMC. In addition, we will recruit Service Members who have a history of a suicide-related event in garrison. We have prepared a brief study description and screening form that will be provided to inform potential participants of the study's eligibility criteria. The screening form will be given to patients by inpatient staff. Patients who may potentially be eligible for the study based on their responses to the screening questions will be asked by inpatient staff if they would like to be contacted by a member of the research team. If the patient expresses interest, a member of the research team will discuss the study and proceed with the enrollment process. The study description and screening form have been approved by the IRBs at all three sites. USUHS study staff will be available to attend Morning Report at WRNMMC to remind inpatient staff about the study in order to facilitate recruitment. We plan to begin enrolling participants at the beginning of the next reporting period.

Reportable Outcomes

Ghahramanlou-Holloway, M., Brown, G., Stanley, B. (2013, February). Management of suicide-related events during deployment. Invited presentation for the Review and Analysis (R&A) Group, W3 Deployment Task Area, Frederick, MD.

Stanley, B., Ghahramanlou-Holloway, M., Brown, G. (2013, May). Management of suicide-related events during deployment. Invited presentation at the United States Medical Research and Materiel Command 'In Progress Review' Meeting, Fort Detrick, MD.

Stanley, B., Ghahramanlou-Holloway, M., Brown, G., (2014, February). Management of suicide-related events during deployment. Invited presentation for the Review and Analysis (R&A) Group, W3 Deployment Task Area, Frederick, MD.

Ghahramanlou-Holloway, M., Brown, G., Stanley, B. (2014, May). Management of suicide-related events during deployment. Invited presentation at the United States Medical Research and Materiel Command 'In Progress Review' Meeting, Fort Detrick, MD.

Ghahramanlou-Holloway, M., Brown, G., & Stanley, B. (2014, August). Management of suicide-related events during deployment. Paper presented at the Annual Military Health System Research Symposium (MHSRS), Fort Lauderdale, FL

Conclusion

The second year has focused heavily on recruitment for the confidential interviews for Study 1 while concurrently developing study measures and obtaining regulatory approvals for Study 2. Recruitment for the Study 1 confidential interviews is ongoing at this time. In order to ensure that study goals are met within the proposed timeline, we have begun recruitment for the Study 1 focus groups and will begin recruitment for the Study 2 confidential interviews with Service Members at the same time.

The early study conclusions have been derived from the confidential interviews completed to date. We have found that the management of suicide-related events during deployment can vary significantly between deployments, and is highly influenced by the deployment setting and resources available. Based on the pilot interviews conducted in preparation for Study 1 recruitment, it appears that decisions made by behavioral health providers and leaders take into account the needs of the suicidal service member as well as the needs of the mission. Based on feedback provided by two military behavioral health providers and a chaplain, it was determined that experiences managing a suicide-related event during deployment differ based on location, context and who is involved. There is also concern about overwhelmingly negative perceptions of behavioral health providers both by those in command and by Service Members. We also concluded the study interview was an appropriate length, questions were clear and targeted, and that responses provided information salient to study aims.

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